40 CFR Part 765

[OPTS-42056; TSH-FLR 2569-5]

Methylolurea and Urea-Formaldehyde Resins; Response to the Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advance notice of proposed rulemaking (ANPR).

SUMMARY: This ANPR is EPA's response to the Interagency Testing Committee's (ITC) designation of methylolurea for priority consideration for health effects testing. The ITC did not recommend chemical fate or environmental effects testing of methylolurea. EPA has tentatively concluded that health effects testing for urea-formaldehyde (UF) resins is warranted under section 4(a) of the Toxic Substances Control Act (TSCA). EPA believes that testing only methylolurea would not be appropriate because methylolurea is an unisolated intermediate and only one of many related components of UF resins. EPA is issuing this ANPR (1) to solicit data on exposure, environmental releases, health effects, chemical fate and environmental effects of UF resins, (2) to solicit information on the chemical composition of the various UF resins, (3) to seek public comments on the criteria for selection of the test substances, and (4) to obtain comments on the testing EPA is considering proposing, including the feasibility of designing studies which will not be confounded by the presence of formaldehyde.

DATE: All comments should be submitted on or before July 20, 1984.

ADDRESS: Written comments should bear the document control number [OPTS-42056] and should be submitted in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Room E-108, 401 M St. SW., Washington, D.C. 20460.

The public record supporting this action is available for inspection in Rm. E-107 at the above address from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St. SW., Washington, D.C. 20460. Toll Free: (800-424-9065). In Washington, D.C.: (554-1404), Outside the U.S.A.: (Operator—202-554-1404).

SUPPLEMENTARY INFORMATION: The Interagency Testing Committee, in its Twelfth Report to the Administrator, published in the **Federal Register** of June 1, 1983 (48 FR 24443), recommended that methylolurea be considered for priority health effects testing. The ITC's recommendation, however, apparently was based on the misconception that methylolurea, identified on the TSCA Chemical Inventory, is a monomer used in the production of urea-formaldehyde resins (UF resins) and controlled release fertilizers. Actually, the product "methylolurea" is not the isolated monomer methylolurea, but a UF resin product. Because the ITC actually evaluated a UF resin product and based its recommendation on tests conducted on UF resins, EPA is treating the ITC recommendation as a recommendation to test UF resins. Accordingly, this Notice seeks to obtain public comments and solicit data and information on the Agency's plans to issue a test rule for UF resins under secton 4(a) of TSCA.

I. Background

Section 4(a) of TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) authorizes the Administrator of EPA to promulgate regulations requiring testing of chemical substances and mixtures in order to develop data relevant to evaluating the risks that such chemicals may present to health and the environment.

Section 4(e) of TSCA established the ITC to recommend to the Administrator of EPA those chemical substances and mixtures that should receive priority consideration for the development of test rules under section 4(a). The ITC may designate up to 50 of its recommendations at any time for priority consideration by EPA. EPA is required to respond within 12 months of the date of designation, either by initiating rulemaking under section 4(a) or publishing in the **Federal Register** reasons for not doing so.

On May 11, 1983, in its Twelfth Report, published in the **Federal Register** of June 1, 1983 (48 FR 24443), the ITC designated methylolurea (CAS No. 1000-82-4) for priority consideration for health effects testing. The ITC's recommendation was based on the positive results observed in two genotoxicity studies which were conducted on a material called UF precondensate (another term for a UF resin). (The ITC referred to this material as "methylolurea," which is a misconception since methylolurea is only one of numerous chemical species present in UF resins.) Accordingly, the ITC recommended a battery of short-term genotoxicity tests be performed on methylolurea. In addition, the ITC recommended that studies be performed to determine the fate of the material in the body. The Committee further recommended that, if these tests and studies increase concern about the potential toxicity additional testing, such as a long-term bioassay, should be conducted.

Chemical fate testing and environmental effects testing of methylolurea were nto recommended because of the predicted low environmental persistence of methylolurea.

Under section 4(a)(1) of TSCA, the Administrator shall by rule require testing of a chemical substance to develop appropriate test data if the Agency finds that:

> (A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,
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> (ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and
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> (iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or
>
> (B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,
>
> (ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and
>
> (iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

EPA uses a weight of evidence approach in making a section 4(a)(1)(A)(i) finding in which both exposure and toxicity information are considered to make the finding that the chemical may present an unreasonable risk. For the section 4(a)(1)(B)(i) finding, EPA considers only production, exposure, and release information to determine if there is substantial production and significant or substantial release. Thus, while EPA can require testing for an effect under section 4(a)(1)(A) only if there is a suspicion of a hazard, under section 4(a)(1)(B) EPA can require testing whether or not there are data suggesting adverse effects if the relevant production and exposure or release criteria are met.

For the findings under both section 4(a)(1)(A)(ii) and 4(a)(1)(B)(ii), EPA examines toxicity and fate studies to

determine if existing information is adequate to reasonably determine or predict the effects of human exposure to or environmental release of the chemical. In making the third finding, that testing is necessary, EPA considers whether ongoing or planned testing will satisfy the information needs for the chemical and whether testing that the Agency might require would be capable of developing the necessary information.

EPA's process for determining when these findings can be made is described in detail in EPA's first and second proposed test rules as published in the **Federal Register** of July 18, 1980 (45 FR 48528) and June 5, 1981 (46 FR 30300). The section 4(a)(1)(A) finding is discussed in 45 FR 48528, and the section 4(a)(1)(B) finding is discussed in 46 FR 30300.

II. Response of EPA to the ITC Report

This ANPR is EPA's response to the ITC; EPA has tentatively concluded that health effects testing is warranted for urea-formaldehyde resins under section 4(a) of TSCA. EPA believes that testing should be performed on the UF resin mixtures rather than on the individual components of UF resins, such as methylolurea. This notice also presents a summary of the Agency's preliminary analyses and the major issues that have been identified during the Agency's evaluation to date of methylolurea and urea-formaldehyde resins, which must be resolved before proposing a test rule.

Because of the misconception contained in the ITC report, EPA's focus in responding to the ITC recommendation is to gather information pertinent to the potential toxicity of the monomeric and oligomeric reaction products of urea after reaction with formaldehyde, and not to focus on the specific chemical methylolurea.

EPA has not identified any reports of toxicological testing on resins which have been characterized by chemical composition, and no reports of testing on the specific chemical substance methylolurea or any other single component chemical of UF resins except formaldehyde. Accordingly, EPA has tentatively determined that its response to the ITC needs to encompass the substance commonly known as UF resins, either the syrupy liquid oligomeric mixture or its dried or reconstituted equivalent (CAS =9011-05-6, also 68611-64-3). This need was implicitly recognized by the ITC which focused much of its discussion on UF resins. EPA is specifically not including in its definition of UF resins being considered for testing at this time the cured plastic-like polymeric material which is commonly produced by acid or heat treatment of the UF resin. The information supporting this determination is discussed in Units III and IV of this notice.

EPA has reviewed the ITC report, the data on which their recommendation was based, information obtained from EPA's own information-gathering activities, and materials submitted to the Agency by the public. EPA's search for available information encompassed the entire range of substances which are variously called UF resins, UFC, UF prepolymer, and UF precondensate, as well as the products called "methylolurea." The information gathering rules under section 8(a) (48 FR 28443, June 22, 1983) and 8(d) (48 FR 24366, June 1, 1983) of TSCA were issued only for methylolurea, CAS No. 1000-82-4. The Agency may develop proposed regulations under sections 8(a) and 8(d) of TSCA to require information reporting for manufacture and production or health and safety studies on UF resins if sufficient information is not received in response to this ANPR.

Publication of an ANPR provides an opportunity for public comment on the difficult issues associated with health effects testing of UF resins before the Agency proposes testing for these chemical mixtures. EPA is unable, at this time, to develop an appropriate testing scheme because of the complications caused by the presence of a dynamic equilibrium among the various chemical species in UF resins, and by the presence of formaldehyde in UF resins. This is explained more completely in Unit III.1. "Chemistry." The alternative of testing individual monomeric or oligomeric components of UF resins presents equally difficult choices, because a great number of possible chemical species can be postulated to exist. In Unit III. EPA identifies over ten different chemical species that can be present in varying proportions, and these do not begin to exhaust the possibilities.

Because these complex issues cannot be readily resolved with available information, the Agency has determined that an ANPR is the most appropriate means of seeking additional information to assist in determining what tests and test materials are appropriate. (see Unit V.) Proceeding with the development of a proposed rule prior to receiving such input could result in needless expenditure of the Agency's resources and considerable delay in promulgating a final rule. This would especially be true if public comments necessitated modification of the criteria which might be proposed for test material selection or reconsideration of the bases for requiring testing to the extent that reproposal would be necessary.

III. General Information

1. *Chemistry.* Urea-formaldehyde (UF) resins are the products which result when urea and formaldehyde are combined in aqueous solution. The components of UF resins are the monomeric and oligomeric reaction products of urea and formaldehyde. Methylolurea is the first and simplest of many reaction products formed, all of which coexist in a dynamic equilibrium. Some of the other reaction products are di- and trimethylolurea, methylenediurea and its mono- and dimethylol derivatives, uron and methyloluron, and oxydi(methyleneurea) and its mono- and dimethylol derivatives. Complete chemical characterization of UF resin components has not been performed; molecular weights of the reaction products range from 200-500 daltons, and oligomers contain up to 5 to 7 urea units.

The characteristics of the UF resins vary according to the pH of the solution and the ratio of formaldehyde to urea as well as the total solute concentration of the material. Unless dehydrated, UF resins are viscous, clear liquids. Polymerization or curing of UF resins is effected by either heat or acid or both to yield a plastic-like material which is non-reactive.

2. *Production.* Slightly over one billion lbs of UF resins are produced yearly (Ref. 1). The public portion of the TSCA Inventory lists total production of 467 million to 2.3 billion lbs of urea-formaldehyde products produced at 137 plant sites for the year 1977. Two producers reported to the TSCA Inventory combined production of 31 to 161 million lbs of "methylolurea", a product which is also called UF monomer or precondensate.

Although the ITC Report gives specific data for the chemical species methylolurea ($C_2H_6N_2O_2$), the CAS No. (1000-82-4) given refers to material which is a reaction product of urea and formaldehyde, and not the chemical species. This "methylolurea" product is indistinguishable from other UF resins. At a September 13, 1983 public meeting to discuss EPA's consideration of how to respond to the ITC recommendation to test methylolurea, a representative of one of these companies which reported manufacturing methylolurea to the TSCA Inventory (Georgia-Pacific Corporation) stated that the particular product it reported to the TSCA Inventory as "methylolurea" does not contain analytically detectable levels of the chemical species methylolurea, and that "methylolurea" was a sales term for certain UF resins.

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UF resins are manufactured in closed systems, either in batches or continuously. If drying is performed, closed systems are used. Some UF resins are used on-site as they are manufactured; others are used off-site. Many have other substances added before use to impart specific desirable properties. UF resins may be dried and packaged for shipment, to be reconstituted at time of use, or they may be shipped in liquid form. Liquid UF resins are not stable on long-term storage, whereas the dried UF resin is relatively stable.

3. *Uses.* The primary use of UF resins is as an adhesive in the manufacture of hardwood plywood and pressed wood products. This use accounts for about 80–85 percent of UF resins produced (Ref. 2).

Particleboard production is a highly automated process; wood chips are mixed with UF resin, formed into mats and hot pressed to the desired thickness. Curing of the UF resin occurs at the pressing stage, then cooled boards are cut, trimmed, sanded, and, sometimes, finished with a UF resin-based coating.

Hardwood plywood is formed by gluing layers of wood veneer together. The UF resin adhesive is most often applied by roller spreaders, although sometimes curtain coating or spray coating is used. Either hot or cold pressing, or radio frequency heat curing, is used to cure the UF resins.

Other significant uses of UF resins are as thermosetting plastics (molding compounds), slow-release fertilizers, fabric finishes, paint additives, and paper finishes (Ref. 3). UF resins are also used in the manufacture of furniture, as adhesives and finishing material, and for many other relatively minor uses.

4. *Occupational exposure.* EPA estimates that approximately 140,000 persons are potentially exposed to UF resins in occupational environments both during manufacture and use. The manufacture of pressed-wood and paper products, and paints and coatings are the major industries where UF resins are used. Other industries which use some resins but primarily use products which were made using UF resins are manufacturers of wood furniture and building components (pre-fabricated wood products).

The major route of exposure to UF resins is believed to be by dermal contact with the liquid resin; inhalation of dust during handling of dried resins or of aerosols from spray applications and subsequent ingestion may also occur. While exposures have not been quantified, EPA believes that some processes, such as plywood manufacture, may expose workers to fairly large amounts of UF resins. Other processes, such as application of UF resin-based paints, may expose workers to much smaller amounts.

5. *Consumer exposure.* EPA expects that few, if any, consumers will be exposed to uncured UF resins. In finished products, the UF resin has been polymerized by some curing process, and EPA does not expect the cured polymeric material to be reactive to any measurable extent. Formaldehyde off-gassing occurs to varying degrees from "cured" products such as pressed-wood products, textile finishes or UF foam; the heavier monomeric and oligomeric components of UF resins are not expected to volatilize under ambient conditions.

6. *Environmental exposure.* The available information concerning manufacturer and use of UF resins indicates that environmental exposures will be of less concern than occupational exposures. The major release of UF resins into the environment is expected to be in wastewater, which would be treated at either wastewater treatment units or surface impoundments.

Additionally, a considerable amount of waste containing 1–10 percent UF resin occurs in the form of semi-solid or solid sludges, which are often disposed in landfills. Accidental spills during transportation are considered to be the next most likely source of environmental exposure. Occasional small releases of aerosols in various manufacturing processes are also possible, as are minor releases of powdered polymer in routine handling.

Controlled-release fertilizers constitute an intentional release to the environment. Their degradation provides a continuous supply of nitrogen to the plants growing in the treated soil. Different formulations degrade at different rates, depending on the degree of polymerization. Longer, more complex chains take more time to be totally mineralized.

7. *Health effects.* EPA has found minimal information concerning health effects for either methylolurea or urea-formaldehyde resins. Those studies which have been located are incomplete because either the test material is not characterized, dose levels are uncertain, or the results are incompletely described.

An in vitro study of *N,N'*-bis(hydroxymethyl) urea characterized cross-linking reactions with tyrosine residues in wool and proposed a similar reaction with nucleic acids (Ref. 4). Another study demonstrated inhibition of mammalian cell growth in culture (Ref. 5). No metabolism, pharmacokinetic, or material balance and distribution studies on any UF resins or component chemicals have been located.

A few studies of acute toxicity of components of UF resins were located. Oral LD_{50} values for *N,N'*-bis(hydroxymethyl) urea are 1,795 mg/kg for mice, 3,400 mg/kg for rats, and 3,200 mg/kg for rabbits (Ref. 6). From another study where mice were pre-treated with 2 g/kg methylolurea prior to dosing with formaldehyde, the oral LD_{50} for methylolurea in mice is likely greater than 2 g/kg (Reg. 7).

On other report concerns dermal application to guinea pigs of two resins characterized only by formaldehyde content (Ref. 8). Erythema, skin dryness, desquamation, and sensitization were noted.

Minimal information concerning subchronic effects was located. Continuous exposure of rats, from birth, to an atmosphere containing volatile material from resin-impregnated wood shavings impaired normal function of six organ systems, including the nervous system, and inhibited growth and development (Ref. 9).

A summary translation to English of a Russian paper describes several different types of toxicological investigations of two resins containing urea, formaldehyde and polyethylenepolyamine. The paucity of details and presence of an additional component in these studies precludes EPA's reliance on this study for the purpose of this evaluation (Ref. 10).

Several feeding studies wherein uncured commercial UF resins were fed to test animals at various doses demonstrate no toxic effects (Refs. 11 and 12). Numerous studies wherein large animals were administered treated feed are available (Ref. 13); may of these were apparently conducted in support of a petition to the Food and Drug Administration to permit use of UF resins in food packaging materials.

Only two mutagenicity studies have been located and both demonstrate positive effects (Refs. 14 and 15); as with other types of studies, the materials tested were not chemically characterized.

N,N'-bis(hydroxymethyl) urea was tested for antitumor activity and found ineffective (Ref. 16).

No definitive studies on the reproductive, teratologic, or nervous system effects of UF resins have been located.

Numerous reports of eczema, dermatitis, and other toxic effects in humans occupationally exposed to UF

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resins were located in the literature, but the extent of exposure and composition of resin are not specified in any report. Furthermore, there are no epidemiological studies concerning the human health effects of UF resins.

IV. Tentative EPA Decisions

1. *Preliminary findings.* EPA has determined that UF resins should be the subject of the Agency's further test rules consideration. EPA has tentatively concluded that there is substantial production of, and human exposure to, UF resins, as summarized in Unit III. Furthermore, the Agency tentatively believes that there are insufficient data and experience upon which the health effects of UF resin can reasonably be determined or predicted, and that testing is necessary to develop such data. Therefore, EPA believes that UF resins meet the criteria for requiring that testing be conducted under TSCA section 4(a)(1)(B).

2. *Tentative conclusions on testing.* EPA believes that exposure, when it occurs, is to the entire range of chemicals which collectively comprise UF resins. Therefore, EPA believes that testing of the UF resins themselves is the appropriate means to determine the health effects of UF resins. EPA has tentatively concluded that a full battery of toxicological testing should be conducted, consisting of mutagenicity, acute, subchronic, neurotoxicity, teratology and reproductive effects, and possibly chronic studies. EPA tentatively believes that testing several substances (encompassing the range of UF resins) in the short-term tests and fewer substances in the long-term tests would likely provide sufficient information to evaluate the health effects of UF resins, but the Agency has not yet developed criteria for selection of test materials at this time. However, the Agency believes that thorough characterization of the materials being tested is essential.

3. *Economic impact.* EPA is still assessing the potential economic impact of the type of testing program described above. Since the Agency is considering extensive testing, the total costs could be substantial, depending on the number of tests required for each resin and the total number of resins that must be tested. The Agency will examine testing needs carefully with respect to UF resins, and seeks public comment on the best way to obtain needed data while not depriving society of the benefits of these chemicals.

V. Issues

EPA solicits comment from the affected industries and the general public on all aspects of its evaluation of UF resins, its tentative decision to require testing, and, in particular, on what substances to test. Specific issues are listed below.

1. *Exposure to UF resins.* EPA is requesting information which will allow it to ascertain when, where, and how occupational, consumer, and environmental exposures occur, and what quantities of UF resins are associated with these exposures.

2. *Health effects of UF resins.* EPA seeks to obtain copies of any toxicological studies which might have been performed on any UF resins. Studies where the composition and physical characteristics of the test material has been or can be established will be particularly valuable.

3. *Chemical composition of the various UF resins.* EPA solicits definitive information on the relative and absolute quantities of the specific chemical species which exist in UF resins and also on the physical and chemical characteristics of individual UF resins, such as pH, urea-to-formaldehyde ratio, and total solute concentration. More specifically, are resins having certain physical and chemical characteristics best suited for different processes? Which ones? How does the chemical composition vary with different physical characteristics?

4. *Environmental releases and exposures.* EPA has determined that UF resins are sometimes discharged into waste water systems or disposed in landfills. The Agency requests information concerning the quantities of UF resins discharged through wastewater facilities and disposed in landfills or released to the environment through other processes.

5. *Chemical fate and environmental effects of UF resins.* The Agency requests data on chemical fate and environmental effects of UF resins to determine if sufficient data exists to reasonably determine or predict the chemical fate and environmental effects of UF resins.

6. *The testing which EPA is considering proposing.* EPA will consider all comments concerning which tests should be conducted to determine the health effects of UF resins. The Agency is particularly concerned that interpretation of any toxicological tests will be confounded by the presence of a dynamic equilibrium among the chemical species, or by the presence of formaldehyde in the test material. Can studies be designed which would avoid such confounding factors? Would it be preferable to attempt metabolic and pharmacokinetic studies which might confirm or negate the role of formaldehyde in UF resin toxicity? How might EPA design a tiered testing scheme which performs a limited amount of testing on a wider range of UF resins and higher tier, long-term testing on fewer materials? Should EPA consider testing the degradability of cured UF resin under ambient conditions? Under high temperature and humidity?

7. *Criteria for selection of test materials.* The Agency solicits comment on whether synthetic mixtures having certain specific characteristics or actual commercial products should be tested. EPA also invites comments on whether it might be more effective to test specific chemical components of UF resins rather than mixtures which are expected to contain variable quantities of individual chemical species. How many different resins, or how many individual chemicals, would be necessary to adequately represent the full range of possible test substances?

EPA would also welcome comments on how best to characterize the test substances, and the extent to which such characterization should be performed.

VI. References

(1) Chemical and Engineering News. (June 14). Production by the U.S. Chemical Industry. Plastics, Synthetic Rubber. p. 37. 1982.

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(7) Horiguchi, Y., Shimuzi, H., Satoh, S. *et al.* Hygienic study on packaging and vessel made of synthetic resin (III). Effects of urea compounds on the toxicity of formaldehyde. Shokuhin Eiseigaku Zasshi 15:440–445. (In Japanese; English abstract) 1974.

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(12) Galibin, G. P., Action of hardened synthetic resins on animal systems. Toksikologiya Novykh Promyshlennykh Khimi Cheskikh Veshchestv 5:45–50. (In Russian) 1963.

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(16) Tarnowski, G. S., Cappuccino, J. G., Schmid, F. A. Effect of 1,3-diallylurea and related compounds on growth of transplanted animal tumors. Cancer Research 27(1):1092–1095. 1967.

VII. Development of Rulemaking

After an analysis of the public comments on the ITC report and review of the available data, EPA tentatively believes that there is reason to proceed with development of a proposed rule for testing of UF resins.

By publishing this ANPR, EPA hopes to receive early comment on the issues set forth, prior to proceeding with rulemaking.

The Agency will analyze all comments, production and use patterns, available data, and other relevant issues raised in comments on this ANPR. The Agency also will consider any testing plans proposed for its review and comment. Any testing plans submitted for the Agency's consideration in the ANPR comments need not be in final form, but they should include formal protocols for proper review.

VIII. Public Record

EPA has established a public record for this ANPR, docket number [OPTS–42056]. The record includes the following information:

(1) **Federal Register** notice containing the designation of methylolurea to the priority list and all comments on methylolurea received in response to that notice.

(2) Communications (public).

(a) Letters.

(b) Contact reports of telephone conversations.

(c) Meeting summaries.

(3) Published and unpublished data.

(4) Technical Support Document, and copies of those references in it which are specifically referred to in this notice.

This record includes basic information considered by the Agency in developing this notice, and is available in the OPTS Reading Rm. E–107, from 8:00 a.m., to 4:00 p.m. on working days (401 M St., SW., Washington, D.C. 20460). The Agency will supplement the record periodically with additional relevant information received.

(Sec. 4, Pub. L. 94–469, 90 Stat. 2003; (15 U.S.C. 2061))

Dated: May 11, 1984.

Alvin L. Alm,

Acting Administrator.

[FR Doc. 84–13564 Filed 5–18–84; 8:45 am]

BILLING CODE 6560–50–M

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